

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Lauren Shern, M.P.H.
Acting Executive Director
Health and Medicine Division

October 25, 2021

RE: NAS Proposal No. 10005660

Rebecca Dzubow, M.P.H., M.A., M.E.M.
Division Director
Office of the Administrator
Office of Children's Health Protection
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code 1107-T
Washington, DC 20460

Dear Ms. Dzubow:

In response to RFP No. PR-ORD-21-02205 / Contract #68HERC19D0011, we are pleased to submit the enclosed proposal on behalf of the National Academy of Sciences, a private federally chartered tax-exempt corporation, prepared by our Board on Population Health and Public Health Practices, requesting support on Children's Environmental Health: A Workshop on Future Priorities for Environmental Health Sciences. The total estimated cost of this project is \$300,000.00 for the period from November 01, 2021 to October 31, 2022, of which the United States Environmental Protection Agency is requested to provide \$300,000.

The responsible staff officer for this study is Elizabeth Boyle, Senior Program Officer. She may be contacted regarding program matters at (202) 334-2228, eboyle@nas.edu. Business negotiations are the responsibility of Robert "Skip" Day, Contract Manager, Office of Contracts and Grants. He may be reached at (202) 334-3873.

We shall appreciate your consideration of this matter.

Sincerely,

Signature Approval via email

Lauren Shern
Acting Executive Director
Health and Medicine Division

Enclosures

Cc: Nica Louie, William M Yates Rose Marie Martinez

500 Fifth Street, NW, Washington, DC 20001
Phone 202.334.2603 E-mail lschern@nas.edu nationalacademies.org/HMD

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

HEALTH AND MEDICINE DIVISION

BOARD ON POPULATION HEALTH AND PUBLIC HEALTH PRACTICE

Proposal No. 10005660

In response to RFP No. PR-ORD-21-02205 / Contract #68HERC19D0011

CHILDREN'S ENVIRONMENTAL HEALTH: A WORKSHOP TO IDENTIFY FUTURE PRIORITIES FOR
ENVIRONMENTAL HEALTH SCIENCES

OCTOBER 2021

Robert "Skip" Day

James Burke for
Director
Office of Contracts and Grants
National Academy of Sciences
Telephone: (202) 334-2428
E-mail: jburke@nas.edu

Rose Marie Martinez

Rose Marie Martinez
Senior Board Director
Board on Population Health
Health and Medicine Division
Telephone: (202) 334-2655
E-mail: rmartinez@nas.edu

This proposal is submitted by the NATIONAL ACADEMY OF SCIENCES (NAS), which assumes full technical and legal responsibility under its Act of Incorporation for the work to be carried out under any resultant agreement. The NAS is a private Federally chartered corporation exempt from federal income tax under Internal Revenue Service Code section 501(c)(3). The NAS Taxpayer Identification Number is 53-0196932. DUNS Number is 04-196-4057. Awards resulting from this proposal should be issued to NATIONAL ACADEMY OF SCIENCES and payment directed to:

National Academy of Sciences
Accounting Office
ATTN: Cash Management Section
500 Fifth Street, NW
Washington, DC 20001
Telephone: 202-334-3351 or 202-334-1476

(rev. 7/7/15)

**THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE
HEALTH AND MEDICINE DIVISION
BOARD ON POPULATION HEALTH AND PUBLIC HEALTH PRACTICE**

PROPOSAL NO: 10005660

**CHILDREN'S ENVIRONMENTAL HEALTH:
A WORKSHOP ON FUTURE PRIORITIES FOR ENVIRONMENTAL HEALTH SCIENCES**

I: SUMMARY

The National Academies of Sciences, Engineering, and Medicine (National Academies) propose to assist the U.S. Environmental Protection Agency (EPA) by holding a workshop that will discuss scientific issues that underpin specific vulnerabilities of children throughout the life course.

The total of \$300,000 is requested from the EPA for full support of this workshop. The work shall be conducted under the auspices of the National Academies' Health and Medicine Division Board on Population Health and Public Health Practice.

II: BACKGROUND

Children may suffer disproportionately from contaminants in the environment. These risks arise because children's neurological, immunological, digestive, and other bodily systems are still developing. Children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults. Children's size and weight may make their bodies less able to protect against harmful exposures, and children's behavior patterns may increase their harmful exposures. To address these unique vulnerabilities, the Environmental Protection Agency (EPA) created the Office of Children's Health Protection (OCHP) in 1997. The OCHP mission is to make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children. The OCHP also ensures that EPA's policies, programs, activities, and standards address disproportionate risks to children that result from the risks to health or to safety that are attributable to products or substances that the child is likely to come in contact with or ingest (such as air, food, water used for drinking or recreation, soil, and products we use or are exposed to).

There have been several efforts to identify environmental health risks to children since 1997. Significant children's environmental health research efforts include the EPA and National Institute of Environmental Health Sciences (NIEHS) Children's Centers, the National Children's Study, and other programs such as the NIEHS Children's Health Exposure Analysis Resource (CHEAR), the NIH Environmental influences on Child Health Outcomes (ECHO), and the NIMH Adolescent Brain Cognitive Development (ABCD) Study. These efforts and others have advanced knowledge of different life stages (prenatal, infancy, early childhood, adolescence) to environmental exposures.

The EPA also has new opportunities to improve children's health protection. The Frank R. Lautenberg Chemical Safety for the 21st Century Act (2016), which amends the Toxic Substances Control Act, calls for the protection of "potentially exposed or susceptible sub-populations ... such as infants, children, (and) pregnant women" from exposure to industrial chemicals. The new provisions allow for greater opportunity to take action to address potential health risks from both new and existing toxic chemicals with explicit considerations for infants, children, and pregnant women.

The U.S. EPA is also interested in exploring how new research could be incorporated in its risk assessment methodology such as:

- Improved understanding of mechanisms leading to early-life windows of susceptibility (e.g., examining possible links between early-life exposure to endocrine disrupters and cancer).
- Better characterization of child-relevant exposure pathways such as soil and dust ingestion.
- How new approach methods (NAMs) for reducing the use of animals in toxicology testing can be used to protect children from environmental hazards.
- Models that more accurately reflect the dynamic and variable nature of growth that can appropriately represent early-life stages, especially given the expanded use of physiologically based pharmacokinetic models in risk assessment.
- Data to illuminate possible links between early-life exposure to environmental chemicals and chronic disease in adulthood (i.e., Barker Hypothesis).
- Improved reporting and application of epidemiology findings in risk assessment, so that the observations in children may be better used in decision-making.

This workshop will serve to engage the children's environmental health research community and other stakeholders in discussions about how advancements in understanding environmental health risks to children will help EPA's OCHP fulfill its mission.

III: STATEMENT OF TASK

A planning committee of the National Academies' Board on Population Health and Public Health Practice and Board on Environmental Studies and Toxicology will organize and convene a public workshop to discuss the state of science and knowledge about children's environmental health. The workshop will bring together experts in epidemiology, toxicology, dose response methodology, and exposure science to explore advancements in understanding the health effects from early life exposures to environmental hazards with effects across the life course, and implications for future priorities. The workshop will feature invited presentations and discussion that may include:

- The state of knowledge on the vulnerabilities of different lifestages (prenatal, infancy, early childhood, adolescence) to environmental exposures.
- Science areas that may be important to advance our understanding of vulnerabilities across early lifestages, including exposures of people of childbearing age.

- Opportunities that may be critical to address and improve consistent application of children's environmental health in risk assessment and regulatory decision making based on existing science.
- Implications of the state of the science to improve policies and programs to protect children's environmental health.

The planning committee will organize the workshop, select and invite the speakers and discussants, and moderate the discussions. The presentations and discussions at the workshop will be documented in a workshop proceeding written by a designated rapporteur in accordance with institutional guidelines.

IV: WORK PLAN

Task 1 – Kick-off call and project milestone chart

EPA is requesting the National Academies to convene a teleconference and provide a "Project Milestone Chart" for this TO.

Subtask 1.1. – Kick-off Call

The National Academies will convene a teleconference with the TOCOR and relevant EPA staff to review the workshop scope, committee identification, proposed milestones and deliverables, and communication plans. This teleconference shall occur within fifteen (15) business days of acceptance of this task order.

Subtask 1.2. – Project Milestones Chart

The National Academies will develop a project milestone chart that details significant activities for each task/subtask and expected progression of the deliverables. This chart shall be provided within thirty (30) business days of task initiation.

Task 2 – Identification of Workshop Planning Committee

The National Academies will appoint a workshop planning committee of approximately 7 experts in the fields of environmental health research, toxicology, epidemiology, risk assessment, pediatrics, environmental health policy, exposure science, environmental and public health ethics, and child development. The National Academies will solicit nominations from the EPA and will consider those candidates with other nominations, but will independently determine who will serve on the workshop planning committee. The committee will be subject to the National Academies policies for bias and conflict of interest determinations. The National Academies will provide EPA with the biographical sketches of the provisional committee, when the committee is posted for the National Academies public comment period. EPA will provide feedback at this time for consideration by the National Academies that will indicate if there are any issues regarding potential conflict of interest (COI) or impartiality within the committee's 20 day public comment period.

Task 3: Workshop Planning Teleconferences & Creation of Webpage

The National Academies will hold teleconferences and create a project webpage.

SubTask 3.1 Workshop Planning Teleconferences

The National Academies will hold several workshop planning teleconferences to discuss the workshop topics, the identification of expert speakers, panelists, and discussants. Planning teleconferences shall begin once the committee is formed and continue through the date of the workshop.

SubTask 3.2 Creation of Webpage to Disseminate Workshop Information

The National Academies will create a project webpage that will house all information related to the workshop. The webpage will include the planning committee members and their biographical information, the workshop registration information, and a draft workshop agenda. The webpage may also provide associated workshop resources such as presentation slides or discussion papers.

Task 4: Experts Workshop

The National Academies will hold a virtual workshop which will be available to the public on the project website.

SubTask 4.1 Conduct Public Workshop by Webinar

The National Academies will develop the public workshop by webinar to gather information from relevant experts and other stakeholders. The National Academies' staff will notify EPA of the date, time, and agenda of the workshop at least one (1) month prior. The National Academies will set up and manage the webinar and provide any technical support for experts' participation. The National Academies will also arrange for a professional science writer to assist the National Academies with the creation of a workshop proceedings. The workshop proceedings is estimated to be approximately 50 pages.

SubTask 4.2 List of Workshop Attendees and Commenters

The National Academies will provide EPA with a list of all workshop participants, speakers, discussants, and panelists, and workshop registrants.

SubTask 4.3 Recording of Workshop Webinar

The National Academies will record the workshop and will post the videos to the project webpage.

Task 5: Summary of Workshop

A National Academies webpage with materials related to the workshop and a summary of the workshop shall be provided.

SubTask 5.1 Workshop Proceedings

The National Academies will provide a pre-publication copy of the workshop proceedings. This proceedings will have been peer reviewed per National Academies' policies and procedures, but it may still require final copy-editing and

formatting for publication. EPA may suggest edits or factual suggestions for consideration in accordance with National Academies' policies and procedures.

SubTask 5.2 Final Professionally Formatted Summary of Workshop

The professionally formatted final proceedings will be delivered to EPA.

SubTask 5.3 Workshop Summary on National Academies Website

The final workshop proceedings will be published by the National Academies Press and will be referenced on the project webpage.

Primary Staff:

Elizabeth Boyle, Senior Program Officer, will serve as the project director. She is an environmental epidemiologist who has been a National Academies program officer since 2015. She has had significant roles in several consensus studies that aimed to understand the impacts of chemical exposures on human health. Currently, she is directing a study sponsored by the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry (CDC/ATSDR) and the National Institutes of Environmental Health Sciences (NIEHS), provide advice for clinicians about per- and polyfluoroalkyl substances (PFAS) testing and how test results should inform clinical care. Ms. Boyle has directed several other projects at the National Academies: The committee to review the EPA's Toxic Substances Control Act Systematic Review Guidance Document, the committee to review EPA's extramural grants program known as Science to Achieve Results (STAR), Acute Exposure Guideline Levels for Selected Airborne Chemicals: Volume 20, Continuous Manufacturing for the Modernization of Pharmaceutical Production, Feasibility of Addressing Environmental Exposure Questions Using Department of Defense Biorepositories, and Lifelong Impact: Why the United States Needs a National Birth Cohort Study. Prior to coming to the National Academies, Ms. Boyle was a senior study director at Westat where she led efforts on exposure assessment in the National Children's Study and supported literature reviews for the EPA, including a review of the epidemiologic studies evaluating the effects of chlorpyrifos exposure on neurodevelopment in children.

DELIVERABLES:

The products of the tasks for activity are as follows:

- a) Task 1, Subtask 1.1. – Within 15 days of acceptance of the task order, the National Academies will convene a kick-off meeting with EPA TOCOR and relevant EPA staff to review the workshop scope and proposed milestones and deliverables.
- b) Task 1, Subtask 1.2. – Within 30 days of acceptance of the task order, the National Academies will provide a project milestone chart to EPA.

- c) Task 2 – Within 3 months of acceptance of this task order, the National Academies will provide appoint a provisional workshop planning committee.
- d) Task 3, Subtask 3.1 – Within 3 months of acceptance of this task order, the National Academies will begin holding conference calls with the workshop planning committee.
- e) Task 3, Subtask 3.2 – Within 6 months of acceptance of this task order, the National Academies will host a webpage with information about the workshop.
- f) Task 4, Subtask 4.1 – One month before the workshop, the National Academies will provide EPA with the workshop date, time, and the draft agenda of the workshop.
- g) Task 4, Subtask 4.2 – Within five business days of the public workshop, the National Academies will provide EPA with a list of all workshop participants, speakers, discussants, and panelists, and workshop registrants.
- h) Task 4, Subtask 4.3 – Prior to the release of the workshop proceedings, the National Academies will release a recording of the workshop on the project webpage.
- i) Task 5, SubTask 5.1 – The National Academies will provide EPA with a pre-publication copy of the workshop proceedings.
- j) Task 5, SubTask 5.2 – Within 4 months following the workshop, the National Academies will provide the professionally formatted final proceedings to EPA.
- k) Task 5, SubTask 5.3 – Before the close of the project, the final workshop proceedings will be published by the National Academies Press and will be referenced on the project webpage.

V: ACCEPTANCE CRITERIA

The Contractor shall prepare high quality products that are reproducible and transparent. Figures submitted shall be of high quality similar to presentations developed for national scientific forums and should be formatted as jpeg or TIFF files. Deliverables shall be edited for grammar, spelling, and logic flow, as well as technical accuracy, completeness, timeliness, and conformance with the specific task, charge and expertise and deliverables of this Performance Work Statement. The technical information shall be reasonably complete and presented in a logical, readable manner. Text deliverables shall be provided in Microsoft Word 2016, Adobe Acrobat or compatible format. Deliverables shall be accepted upon review and approval by the TOCOR.

VI: PUBLIC INFORMATION ABOUT THE PROJECT

In order to afford the public greater knowledge of National Academies' activities and an opportunity to provide comments on those activities, the National Academies may post on its website (<http://www.nationalacademies.org>) the following information as appropriate under its procedures: (1) notices of meetings open to the public; (2) brief descriptions of projects; (3) committee appointments, if any (including biographies of committee members); (4) report information; and (5) any other pertinent information.

VII: FEDERAL ADVISORY COMMITTEE ACT (FACA)

Section 15 of the Federal Advisory Committee Act, 5 U.S.C. App., Section 15, does not apply to the activities described in this proposal. Section 15 of FACA restricts agency use of any advice or recommendations provided by the National Academies that were developed by use of an Academy committee under an agreement with a Federal agency unless certain requirements are met. Those requirements do not apply to the work described in this proposal because the work does not involve either the use of an Academy committee or the provision of any advice or recommendations to a Federal agency.

THE NATIONAL ACADEMY OF SCIENCES

HEALTH AND MEDICINE DIVISION

BOARD ON POPULATION HEALTH AND PUBLIC HEALTH PRACTICE

Proposal No. 10005660

Children's Environmental Health: A Workshop to Identify Future Priorities for Environmental Health Sciences

EPA Cumulative Summary Estimate of Costs

11/1/21 to 10/31/22

Ex. 4 CBI

It is requested that the contractor provide for payment via Letter of Credit or electronic transfer.

Footnote: These major cost categories reflect the billing structure used by the National Academy of Sciences. Cost and rate data are attached as background information. Please be advised, however, that all costs are systematically collected in our accounting system and are available for audit through arrangements with the Defense Contract Audit Agency and our cognizant Administrative Contracting Officer at the Office of Naval Research.

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HEALTH AND MEDICINE DIVISION

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Proposal No. 10005660

Children's Environmental Health: A Workshop to Identify Future Priorities for Environmental Health Sciences

Estimate of Costs

11/1/21 to 10/31/22

12 months

Ex. 4 CBI

Ex. 4 CBI

It is requested that the award will provide for payment
via Letter of Credit or electronic transfer.

Ex. 4 CBI

Ex. 4 CBI